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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,092	02/06/2004	Ernesto A. Brovelli	AM1150	7125

28533 7590 06/15/2007

IN RE: ALTICOR INC. 28533
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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,092	BROVELLI ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/16/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/16/07 has been entered.

Claims 1, 3, 5-7 and 23-25 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

The previous rejection made over claims 1, 3, 5-7 and 23-25 with regard to New Matter (35 USC 112 First paragraph) are removed due to Applicant's persuasive arguments that the specification as filed taught wherein translational products from macrophage cells were tested in response to introduction with Echinacea extracts.

It is noted that the species of 'marker compound', polysaccharide', in claim 5 has been examined on the merits. Rininger specifically teaches that polysaccharides from Echinacea were well known in the art to be immunopotentiating agents (see page 2 of Rininger as well as Examiner's statements, *infra).* Thus, the election of species with regard to this species is hereby removed.

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is newly deemed that Applicant was not in possession of the scope of claim 1 at the time the Invention was made. Applicant has only disclosed one species of plant; i.e., Echinacea which was studied with regard to phenolic content and immunopotentiating activity. It is deemed that Echinacea is not a representative example of all medicinal plants as broadly stated by claim 1 as there are *hundreds of thousands of known medicinal plants*. Lacking any other representative examples within the specification which would indicate that Applicant was in possession of such a method broadly directed toward all, or at least a representative number of medicinal

plants at the time the Invention was made, it is deemed that the disclosure as originally filed does not possess adequate written description for the genus of 'medicinal plants' as Instantly claimed.

Claims 1, 3, 5-7 and 23-25 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office Action.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues that page 24 of the specification "explains that the chicoric acid concentrations measured and reported at Table I on page 6 of the specification represent variations in chicoric acid levels that generally are accepted by those skilled in the art" (p. 7, Remarks). However, the specification specifically states:

> [0024]The levels of chicoric acid measured during maturation stages 1-6 for Echinacea purpurea are substantially similar or substantially equivalent. Echinacea plants harvested during maturation stage 7 are less commercially desirable due to the drop in the levels of chicoric acid observed at this stage. In other words, **the variation between the chicoric acid levels listed in Table 1 are within the levels generally accepted by those skilled in the art to be variation between individual plants or to be variations within acceptable tolerances for these types of analyses.** (emphasis added)

Here, it is not clear that Applicant has disclosed what an acceptable amount of chicoric acid levels would be. Rather, it is only determined from this statement that the variation of chicoric acid levels is what is accepted. In the claims, Applicant is attempting to claim a particular range of concentrations of marker compounds (it is noted that the claims are not limited to chicoric acid) including chicoric acid, however, it is not clear what the amount (or range) of chicoric acid or any other marker compound is.

Claim Rejections - 35 USC § 103

Claims 1, 3, 5-7 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over A in view of C or B in view of C; wherein A = Seidler – Lozykowska et al. (2003), B= Dou et al. (2001 – Abstract) and C= Rininger et al. (2000). Seidler – Lozykowska et al. may be referred to as SL et al for the reasons keenly discussed in the previous Office Actions.

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues that the cited references "specifically teach against the possibility of combining the characteristics of (1) the standardization of an Echinacea extract to a particular polyphenol or phenolic acid level and (2)

> maximization of the immunostimulatory activity of an Echinacea extract. This is significant because as written, the claims are directed to a method for determining optimal harvest window of Echinacea plants that are to be used to prepare a standardized Echinacea extract by selecting the maturation stage that has both a concentration of a marker compound, such as chicoric acid, that is acceptable for standardization, and the highest level of immune-stimulatory product (p. 8, Remarks).

First, Applicant has not submitted convincing arguments which would indicate that the prior art 'specifically teach against' the claimed invention. First, Applicant alleges that standardization of the Echinacea extract is one of the unique characteristics of the claimed invention. However, it is noted that there is no particular step in the claims which requires standardization of the Echinacea extract. Claim 1 newly recites 'wherein the medicinal plant is used to prepare a standardized extract of the medicinal plant'. This is not a step, but merely an intended use of the plant.

Applicant argues that 'Dou nor Seilder-Lozykowska suggest looking for references that discuss the immunostimulatory activity of Echinacea, or suggest that a harvest time might be selected based on the ability to increase the immuno-stimulatory activity of an Echinacea extract' (p. 9, Remarks). However, to reiterate from the previous Office Action:

> ...the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law (see page 9).

Applicant argues that Rininger teaches that "...chemically standardized Echinacea extracts are inactive as immunostimulatory agents"..."Thus Rininger teaches against using standardized Echinacea extracts, or the active constituents of standardized Echinacea extracts, when seeking to achieve an immunostimulatory effect using an Echinacea extract" (pp. 9-10, Remarks). However, first, it is noted that Rininger only teaches that the 4% phenolic standardized extracts did not induce macrophage stimulation (see page 8). This does not indicate that *all extracts* from Echinacea standardized for chicoric acid will be inactive for immunopotentiating activity.

Further, as discussed above, under the 35 USC 112 Second paragraph rejection, the metes and bounds of term 'acceptable' is unknown. It is deemed therefore that the claims are directed toward choosing *any level* of 'marker compound' such as chicoric acid or other marker compounds. Further, the claim states 'acceptable for standardization'. What concentration is this? It is deemed that the extract may be standardized in terms of the 'highest level of transcriptional product' or even other markers not specifically claimed *because the claims do not state that the extract is actually standardized.* For example, a concentration of 0% chicoric acid would be 'acceptable' to standardize the extract for immunopotentiating activity because the immunopotentating activity would be selected in terms of transcriptional products produced from the macrophages *in-vitro* and would not depend upon the level of chicoric acid present in the extract.

Further, it is noted that the only claim which specifically identifies chicoric acid as the 'marker compound' is claim 5, wherein chicoric acid is among other species of 'marker compounds' in a Markush group of species. Polysaccharides are another species found in claim 5. Rininger specifically establishes that isolated polysaccharides were well known to produce immunostimulatory activity in macrophage and mononuclear cells (see page 2, second full paragraph). Thus, choosing an extract from a harvest time of Echinacea which possessed some amount of polysaccharide and the highest amount of transcriptional product would have been well within the purview of the ordinary artisan at the time the invention was made.

It is further noted that Rininger was specifically aware of the effects of harvest time in conjunction to immuno-potentiating activity: " With the demonstrated reproducibility of the test system (Fig.2), these data highlight the variability of natural products and, for Echinacea, could represent non-optimal harvest time....". Here, it is clear that Rininger recognized the importance of harvest time with regard to immuno-potentiating activity. Again, because the samples of Figure 2 were from different lots of Echinacea products, it is deemed that these products were more than likely harvested at different times (the chance that two commercial products of Echinacea were harvested at the same exact time are very low). One of ordinary skill in the art would have been motivated to chose the extract which contained the highest amounts of transcriptional products in order to manufacture an Echinacea extract with optimum

immune system potentiating activity. One of ordinary skill in the art would have been further motivated to check for the concentration of markers such as chicoric acid and polysaccharides because these were well-known medicinally active agents of Echinacea. Here, it would have been obvious to one of ordinary skill in the art to assay the extract for marker compounds. The claims do not state that the marker compounds must be present at any effective amount, or even at any amount at all.

On page 10, Applicant merely summarizes the arguments as set forth *supra*.

For the reasons set forth *supra*, as well as in previous Office Actions, it is deemed that the claimed invention was obvious over the prior art references.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

May 31, 2007